510(K) Summary, Special 510(k) K11
Page 1 of 2

K111098

Submitter: Imaging Dynamics Company, Ltd.
151, 2340 Pegasus Way N.E.
Calgary, Alberta, Canada T2E 8M5
Tel: 403.251.9939
Fax: 403.251.1771
www.imagingdynamics.com

MAY 27 2011

Date prepared: March 25, 2011
Contact person: Nichole Wheery
Quality Assurance and Regulatory Affairs Manager

1. **Identification of the Device:**
   Proprietary-Trade Name: **innovaXion FP (various models)**
   Classification Name: System, x-ray, stationary, KPR and solid state x-ray imager (flat panel/digital imager), MQB
   Common/Usual Name: Stationary Diagnostic X-ray System with Digital Panel

2. **Equivalent legally marketed devices**:
   - K071402 X3C 1600 plus Digital Radiographic System, IDC (Imaging Dynamics Company)
   - K102123, Vizion DR, Viztek
   - K090742, LTX240AA01-A, Samsung

3. **Description of the Device**: The innovaXion FP represents a modification of our own predicate K071402 X3C 1600 plus Digital Radiographic System. We now support the 510(k) cleared Samsung digital panel. The other radiographic equipment is identical to that supplied by Viztek in K102123. We will market the product in four possible configurations:
   - innovaXion FP 1600 Plus
   - innovaXion FP (flat panel as a retrofit package with Magellan FP software)
   - Magellan (software)

4. **Indications for Use** (intended use): Intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions. Not intended for mammography.

5. **Safety and Effectiveness,** comparison to predicate device. This modified device has the same indications for use and technological characteristics as the predicate devices, in fact employing the predicate devices in the end product. The only difference is adding a new panel (cleared separately) and requisite software. This device is identical to the Viztek predicate except for the DICOM software.

6. **Description of Testing:** Clinical images were acquired and compared to our predicate images. There were no significant differences between them. We also performed software validation testing. The results of clinical, bench, safety test, and software validation testing indicates that the new device is as safe and effective as our predicate device. The modified device conforms to US Performance Standards and the hardware is CSA Listed to US Standards for safety for medical devices. The digital receptor panels are UL listed to US Standards for safety for medical devices.

7. **Conclusion:** After analyzing risk analysis, software validation, safety testing data, and clinical images, it is the conclusion of IDC that the innovaXion FP software is as safe and effective as the predicate devices, have almost no technological differences, and has identical indications for use, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Imaging Dynamics Co., Ltd.
% Mr. Daniel Kamm
Principal Consultant
Kamm & Associates
8870 Ravello Ct
MAPLES FL 34114

MAY 27 2011

Re: K111098
Trade/Device Name: innovaXion FP (various models)
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Regulatory Class: II
Product Code: MQB
Dated: April 12, 2011
Received: April 20, 2011

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111098

Device Name: innovaXion FP (various models)

Indications For Use:

Intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions. Not intended for mammography.

Prescription Use X AND/OR Over-The-Counter Use ___.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S. Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111098